IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Civil Action No. 3:18-cv-14895-BRM-DEA

Plaintiffs,

v.

SANDOZ INC.

Defendant.

LOCAL PATENT RULE 4.3 JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3, Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par") and Defendant Sandoz Inc. ("Sandoz") hereby submit this Joint Claim Construction Statement with respect to the asserted claims of U.S. Patent Nos. 9,375,478 ("the '478 patent"), 9,744,239 ("the '239 patent), 9,687,526 ("the '526 patent); 9,750,785 ("the '785 patent"), 9,744,209 ("the '209 patent"), 9,937,223 ("the '223 patent") (collectively, the "patents-in-suit").

A. CONSTRUCTION OF CLAIM TERMS ON WHICH THE PARTIES AGREE.

The Parties have not reached agreement on the construction of any claim terms. The parties agree that any alleged indefiniteness issues not raised at this time are reserved for trial.

B. PARTIES' PROPOSED CONSTRUCTIONS OF DISPUTED CLAIM TERMS AND IDENTIFICATION OF SUPPORT.

The Parties dispute the proper construction of the following claim terms:

Term for Construction	Claims
"vasopressin"	All asserted claims from all patents.

"administering to the human a unit dosage form"	'478 Patent Claims 1-11 '209 Patent Claims 1-13
"intravenously administering the pharmaceutical composition to the human"	'526 Patent Claims 1-15, 20
"administering the diluted unit dosage form to the human by intravenous administration"	'239 Patent Claims 1-19
"intravenously administering the portion[/second portion] of the pharmaceutical composition to the human"	'223 Patent Claims 1-11
"wherein the impurities are determined based on"	'209 Patent Claim 11 '785 Patent Claim 2
"consists essentially of"	'478 Patent Claims 1-11
"wherein the human's mean arterial blood pressure is increased within 15 minutes of administration"	'239 Patent Claim 5 '478 Patent Claim 3 '526 Patent Claim 5

The chart in the attached Exhibit A sets forth the Parties' respective positions concerning the proposed construction of each of these disputed claim terms, together with an identification of the intrinsic evidence and extrinsic evidence the Parties allege support their respective proposed constructions. The Parties reserve the right to rely in briefing or argument upon any of the intrinsic or extrinsic evidence cited by the Parties for a particular term irrespective of who identified such evidence.

C. TERMS WHOSE CONSTRUCTION WILL BE MOST SIGNIFICANT TO THE RESOLUTION OF THE CASE.

<u>Par's Position:</u> Par does not believe that the construction of any term is case dispositive. However, the Court's construction of the identified "administration" limitations will be most significant to the resolution of the case as it implicates five of the six asserted patents.

<u>Sandoz's Position</u>: Sandoz identifies the following three sets of disputed terms as the most significant to the resolution of the case:

(1) Construction of the "administration" limitations, is claim dispositive because,

under Sandoz's proposed construction of this term, Sandoz would not infringe the asserted claims

of the '478, '209, '526 and '223 patents.

(2) Construction of "wherein the impurities are determined based on" is claim

dispositive because, under Sandoz's proposed construction of this term, Sandoz would not infringe

claim 11 of the '209 patent or claim 2 of the '785 patent and because construction of this term

bears on the validity of claim 2 of the '785 patent under 35 U.S.C. § 112(b).

(3) Construction of "consists essentially of" is claim dispositive because construction

of this term bears on the validity of claims 1-11 of the '478 patent under 35 U.S.C. § 112(b).

D. ANTICIPATED LENGTH OF TIME NECESSARY FOR CLAIM

CONSTRUCTION HEARING.

At the present time, the Parties anticipate that the length of time necessary for the claim

construction hearing should not exceed 3 hours.

E. WITNESSES FOR CLAIM CONSTRUCTION HEARING.

At present time, the Parties do not anticipate that they will seek to present live witness

testimony at the Claim Construction Hearing, but reserve the right to do so upon review of the

claim construction briefs and any supporting expert declarations filed in this matter.

DATED: July 19, 2019

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3

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2019, I caused a true and correct copy of the foregoing PAR'S LOCAL PATENT RULE 4.3 JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT to be served on all counsel of record via the Court's CM/ECF system and via email on the following:

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